DOCUMENT VERIFICATION

Prior to using this document, the user is responsible for verifying that the revision and effective date are current.

REVISION HISTORY

Rev.	Effective Date	Changes Made to Document
1	19-May-2022	First Issue

1. Content

2. Introduction

The LFD kit is an IVD medical device intended by DHSC to be used *in vitro* for the examination of combined throat and nasal specimens derived from the human body solely for the purpose of providing information concerning Covid-19 infection. The device is classified as a **IVD Device for self-testing.**

The PSR report outlines, analyses and reports on the activities that were undertaken by DHSC to ensure the performance and safety of the DHSC LFD during its life cycle in line with the PMS Procedure and PMS Plan.

This was performed thorough the continuous data generation and assessment of the DHSC LFD performance post market and aims to discuss (through presentation of data) the questions below:

a) Were there any new hazard or hazardous situation(s) identified for the DHSC LFD's or has the risk acceptability changed?
b) Has any misuse of the DHSC LFDs occurred?
c) Do the DHSC LFD's still meet the user's needs after medium/long term clinical use?
d) Do users experience any usability issues?
e) Are there any recurring quality issues DHSC LFD's and can significant increasing/decreasing trends be identified for DHSC LFD' inadequate performance?

Refer to **Table 5** for conclusions.

3. Reference documents

Doc ID	Doc name	Revision
QM-01	Quality manual	1
QOP-25	Post- Market Surveillance (PMS) Procedure	3
PMS-0001	PMS Plan for the DHSC COVID-19 LFD device (3 and 7 kit)	2
RMF-001	Risk Management File	5
QP08-F02	LFD Hazard Traceability Matrix	1

Table 1: Reference to internal documentation

4. Standards and guidelines

- ISO 9001:2000 Quality management systems – Requirements.
- ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes.
- ISO 14971:2019 Medical devices -- Application of risk management to medical devices.

5. Methodology

- Data is gathered as per the PMS Plan referenced in Table 1.
- All inputs are stored in a centralised LFD PSR location on SharePoint
- All inputs are submitted via the relevant departments as per the PMS plan.

6. Findings /Results

6.1 In-House manufacturing inspection at Biotime

There were no inspections carried out between the reporting period of 9th Apr and 6th May 2022 following conclusion of QC of the previous contract on 30/01/2022. No further Innova product has been procured during this reporting window.

6.2 Receiving inspection - Intertek Testing in the UK

A total of 5,335 samples underwent validation from the 9th Apr until 6th May 2022, from 51 lots. From these samples, there was one red flag where the control line failed to develop for sample number MFA51691293. Due to this issue falling within the AQL limits of acceptance, all lots passed validation and were accepted into the supply chain. A non-conformance report will be instigated as an action from this report to ensure monitoring of the affected lot number.

(Refer to Attachment 8)

6.3 Product complaints & Qualtrics Survey Reports

- The number of kits distributed in this reporting period is **~ 8.16 million** which is decrease of **~80.84 million** over the previous reporting month.

- A total of 9 complaints were received from Qualtrics, MHRA Yellow card and 119 Call in this reporting period and were discussed at the weekly incident review meetings and weekly Patient safety panel meetings.

- All 9 of those complaints were defined as non-reportable as per Med Dev 12.1 Rev 8.

- A total of 68 user reports were received from the Qualtrics survey in relation to the DHSC LFD during this reporting window.

- No Lot specific trend was identified in this reporting window.

- Further information on the trending categories, number of complaints, reportability/non-reportability, investigations and further actions is documented in Table 2.

(Refer to attachment 02.1)

Qualtrics and Yellow card complaints investigation				
Trending category	**Number of complaints**	**Reportability**	**Investigation**	**Further actions**
Missing components	37	Not reportable	Corrective actions were taken as part of the previous SCAR raised with the supplier. The complaints received are for the batches which were delivered before the corrective action were implemented. There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Damaged Item	1	Not reportable	No action required	Complaints will be monitored for trending purposes
Contaminated Item	1	Not reportable	No action required	Complaints will be monitored for trending purposes
Faulty test results	5	Not reportable	There was no trend observed for any particular batch.	Most of the complaints were back dated yellow card received from MHRA. Corrective actions were taken as part of the previous SCAR raised with the supplier. The complaints received are for the batches which were delivered before the corrective action were implemented. However, the list of these complaints has been passed to the supplier for their visibility.
Faulty items	8	Not reportable	There was no trend observed for any particular batch.	No further action. Complaints will be monitored for trending purposes
Empty extraction buffer	2	Not reportable	Corrective actions were taken as part of the previous SCAR raised with the supplier. The complaints received are for the batches which were delivered before the corrective action were implemented. There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes
Usability	3	Not reportable	There was no trend observed for any specific type of usability issue.	No further action, complaints will be monitored for trending purposes.

Insufficient buffer solution	2	Not reportable	Corrective actions were taken as part of the previous SCAR raised with the supplier. The complaints received are for the batches which were delivered before the corrective action were implemented. There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes
Bar code/QR code issues	10	Not reportable	Complaints forwarded to NHS digital team for investigation	No further action.

Table 2: Summary of reportability/non-reportability for all complaints

*Not reportable: these complaints did not meet the reportability criteria set out in MED DEV 2.12 rev 8 vigilance standard and hence were decided to be non-reportable.

MED DEV 2.12 rev 8 vigilance Guidance to support discussions at Incident Review Meetings & Patient Safety Panel:

- *Question A "Has an event occurred etc."*
- *Question B "Is DHSC device cause of incident"*
- *Question C "Has the event led to death or serious deterioration in health"*

6.4 Complaints Trending

Current trending categories analysed through the Qualtrics data are grouped into three main categories:

1) **Material:** this includes trending categories: Missing item, Damaged Item, Faulty item, Contaminated Item, QR code issues, Empty Buffer Solution Sachet, Insufficient Buffer Solution. Number of complaints is well below the trigger threshold for this reporting period.

2) **Faulty Test Results:** No sub-categories exist within this category of complaints. Number of complaints for this category is well below the trigger threshold for this reporting period.

3) **Harm & Allergy:** this includes complaints from Patient Injury and Allergic reactions as sub-categories. Harm-allergy complaints for this reporting period is 0 and therefore the alert was not triggered.

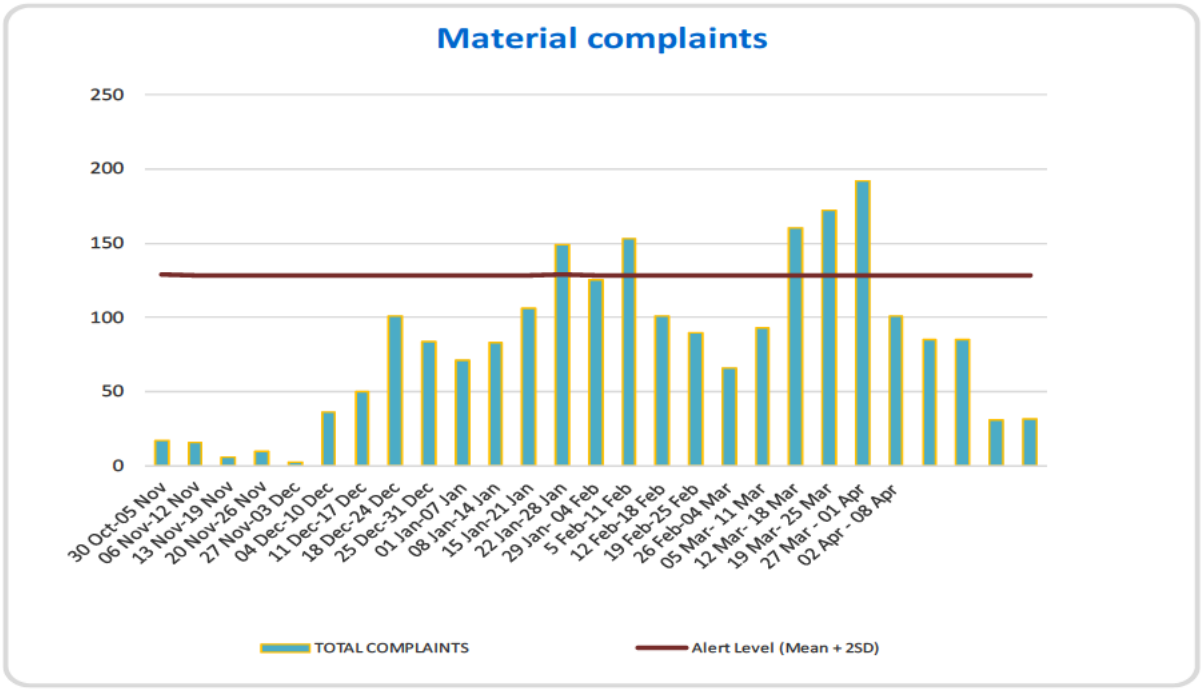


Figure 1: Material complaints weekly trending

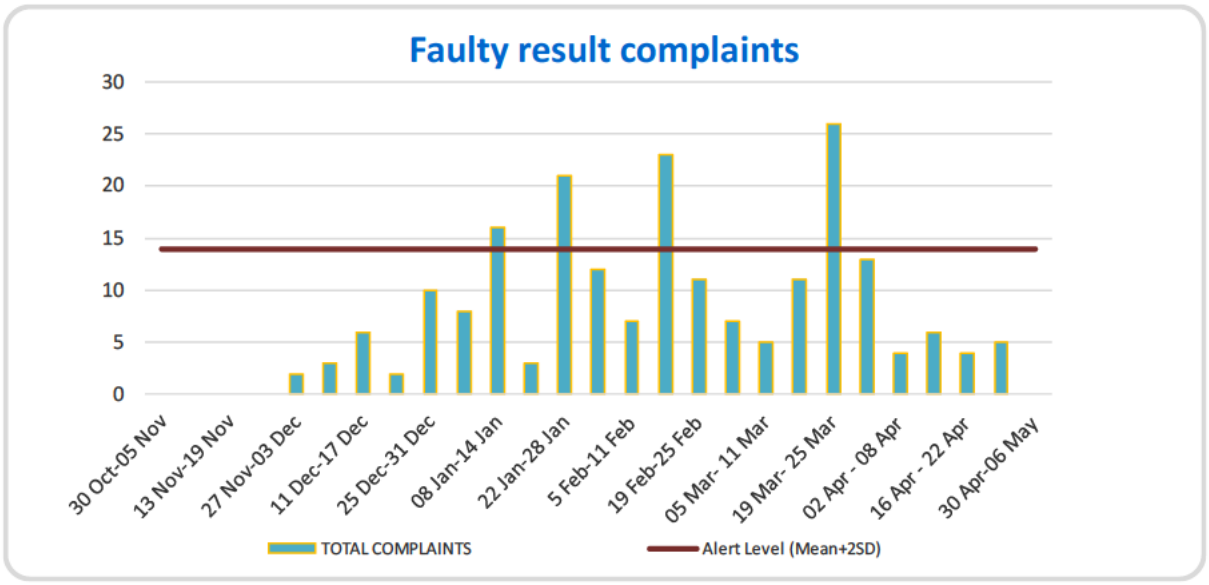


Figure 2: Faulty results complaint weekly trending

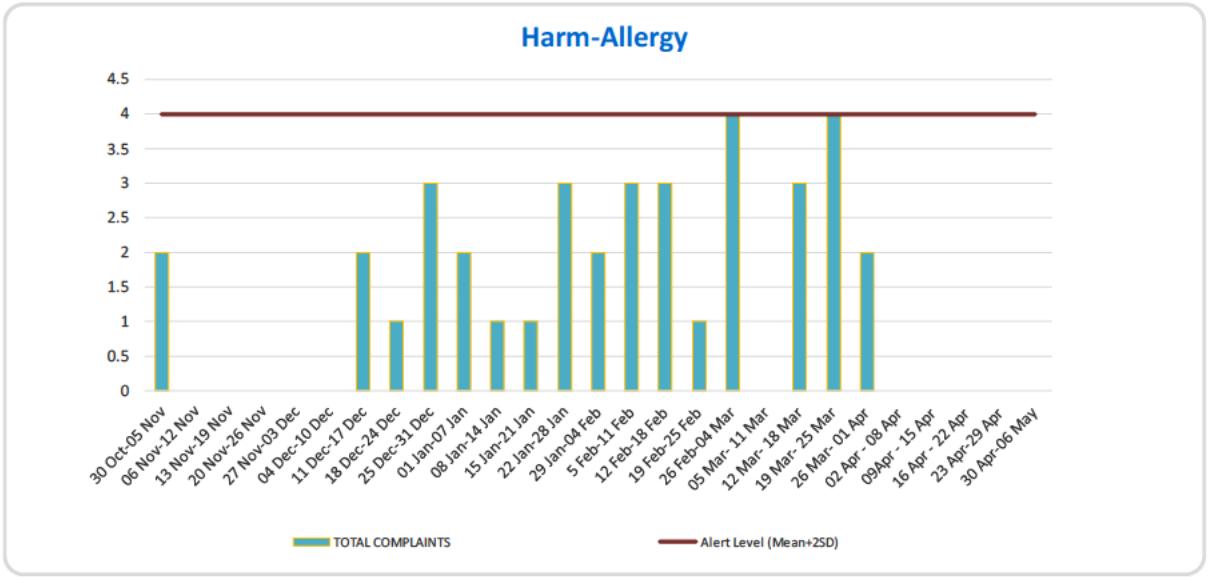


Figure 3: Harm-Allergy complaints weekly trending

(Refer to Attachment 2.2)

6.5 Qualtrics Survey (User Experience)

A total of 616 user responses were received during this reporting window of 9th Apr – 6th May all LFD products for which the DHSC is either the legal manufacturer or distributor.

46.10% of these responses were related to the DHSC LFD Products (**highlighted in green in Attachment 2.3**). 352 users completed 100% of the survey in an average time of 7.8 minutes.

A series of questions relating to the user's overall experience can be seen in **Attachment 2.3**. Satisfaction rates were predominantly above 70% for most queries relating to the usability of the LFD products, except for:

1) ***Reporting of results (Understanding of IFU):*** 57.82% satisfaction rate which is a reduction on the last reporting period by 7.29%.
2) ***Reporting of results (Difficulty of process):*** 50.44% satisfaction rate which is a reduction of 7.81% since the last reporting period.

On-going product improvements are supported at the procurement stage by the LFD Product Management team and information on user experience from the Qualtrics survey is to be shared with the team for continual improvement. As discussed in previous reporting periods, actions have already been instigated at the next round of invitation to tender (ITT). Further information has been retained in this PSR from the previous reporting period and referenced in **Section 6.6.**

(Refer to Attachment 2.3)

6.6 Product Management (Usability Studies)

The LFD Product Team are involved in a Three-Stage process aimed at continuously improving the usability of LFD products sourced by DHSC and supplied to the end users (see Figure 4).

The team have carried out usability research activities with 2000 users through a mixture of surveys and one to one interview. The purpose of this research is to understand (from the user's perspective) what improvements can be made to the LFD product supplied.

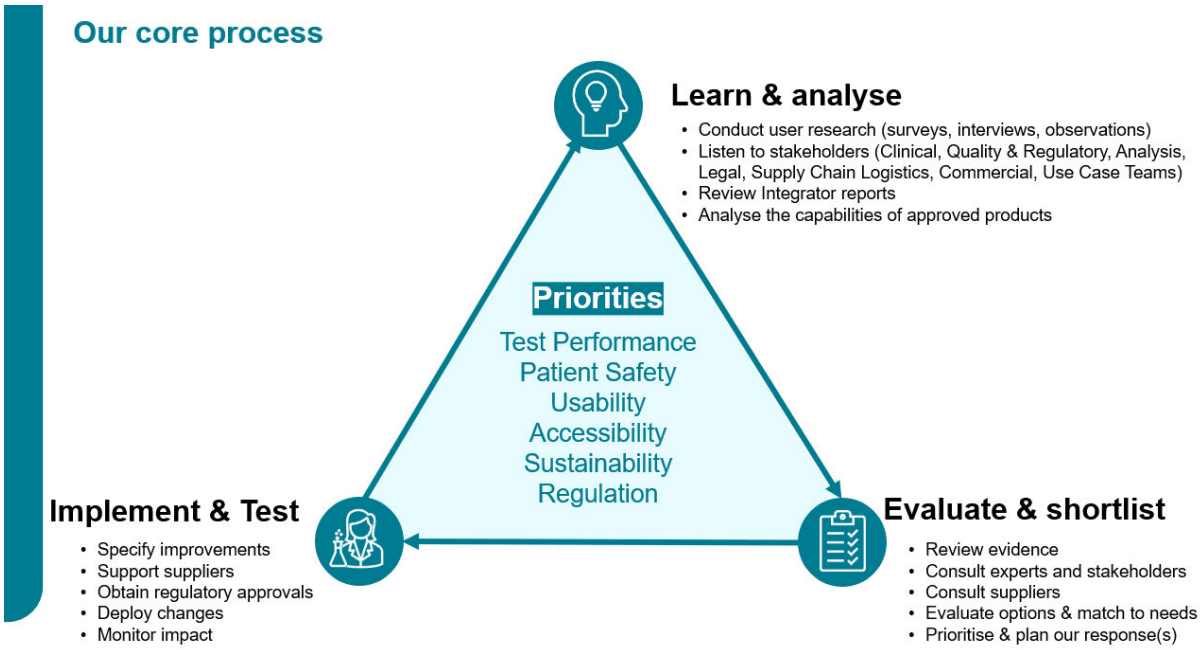


Figure 4: LFD Product Management Teams Core Process

Findings from these usability studies feed into improvements in the procurement exercises (Invitation to Tender ITT).

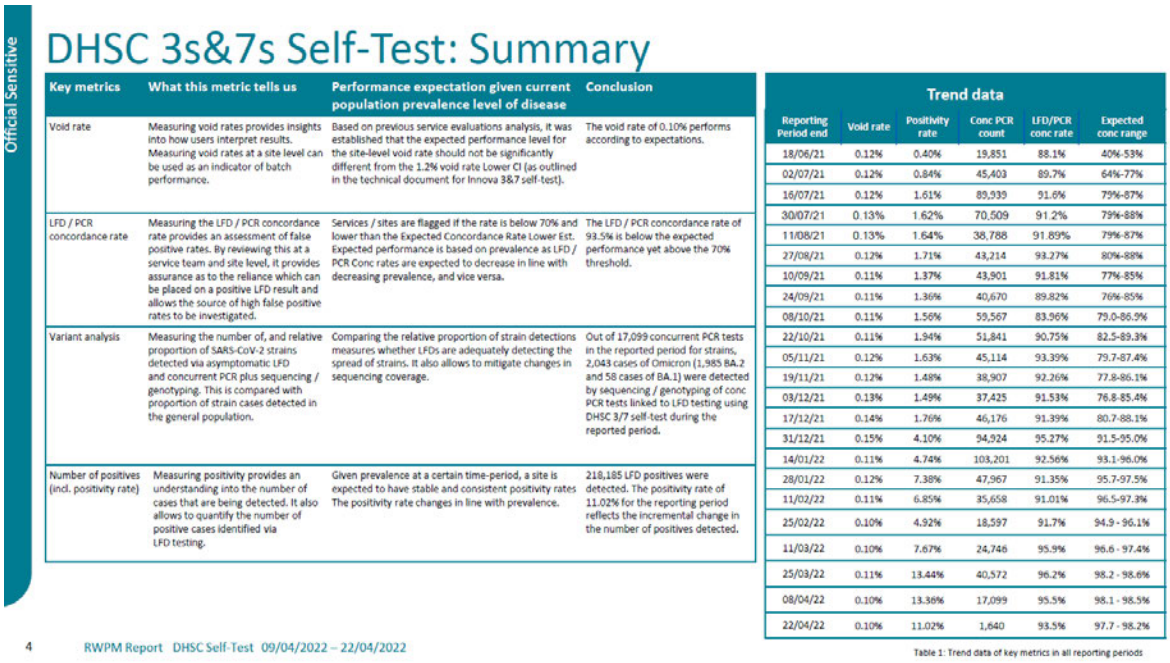
Further information on some of the findings and actions were shared in the previous report and have therefore been omitted from this submission.

No further updates or planned studies are planned from the LFD Product Management team as sufficient data has been collected for the current range of LFD's. Any future studies planned will be discussed in the PSR report.

6.7 Real World Performance Monitoring

The Real-World Performance Monitoring Team carry out routine performance of device and service performance using real-world data generated within NHS Test & Trace covering all services and devices.

Below are summaries for the Void rates, confirmatory PCR rates, variant analysis, and the number of positives (i.e., positivity rates), for the reporting period 9th Apr 2022 – 06th May 2022.



Official Sensitive

DHSC 3s&7s Self-Test: Summary

Key metrics	What this metric tells us	Performance expectation given current population prevalence level of disease	Conclusion
Void rate	Measuring void rates provides insights into how users interpret results. Measuring void rates at a site level can be used as an indicator of batch performance.	Based on previous service evaluations analysis, it was established that the expected performance level for the site-level void rate should not be significantly different from the 1.2% void rate Lower CI (as outlined in the technical document for Innova 3&7 self-test).	The void rate of 0.10% performs according to expectations.
LFD / PCR concordance rate	Measuring the LFD / PCR concordance rate provides an assessment of false positive rates. By reviewing this at a service team and site level, it provides assurance as to the reliance which can be placed on a positive LFD result and allows the source of high false positive rates to be investigated.	Services / sites are flagged if the rate is below 70% and lower than the Expected Concordance Rate Lower Est. Expected performance is based on prevalence as LFD / PCR Conc rates are expected to decrease in line with decreasing prevalence, and vice versa.	The LFD / PCR concordance rate of 93.5% is below the expected performance yet above the 70% threshold.
Variant analysis	Measuring the number of, and relative proportion of SARS-CoV-2 strains detected via asymptomatic LFD and concurrent PCR plus sequencing / genotyping. This is compared with proportion of strain cases detected in the general population.	Comparing the relative proportion of strain detections measures whether LFDs are adequately detecting the spread of strains. It also allows to mitigate changes in sequencing coverage.	Out of 17,099 concurrent PCR tests in the reported period for strains, 2,043 cases of Omicron (1,985 BA.2 and 58 cases of BA.1) were detected by sequencing / genotyping of conc PCR tests linked to LFD testing using DHSC 3/7 self-test during the reported period.
Number of positives (incl. positivity rate)	Measuring positivity provides an understanding into the number of cases that are being detected. It also allows to quantify the number of positive cases identified via LFD testing.	Given prevalence at a certain time-period, a site is expected to have stable and consistent positivity rates The positivity rate changes in line with prevalence.	218,185 LFD positives were detected. The positivity rate of 11.02% for the reporting period reflects the incremental change in the number of positives detected.

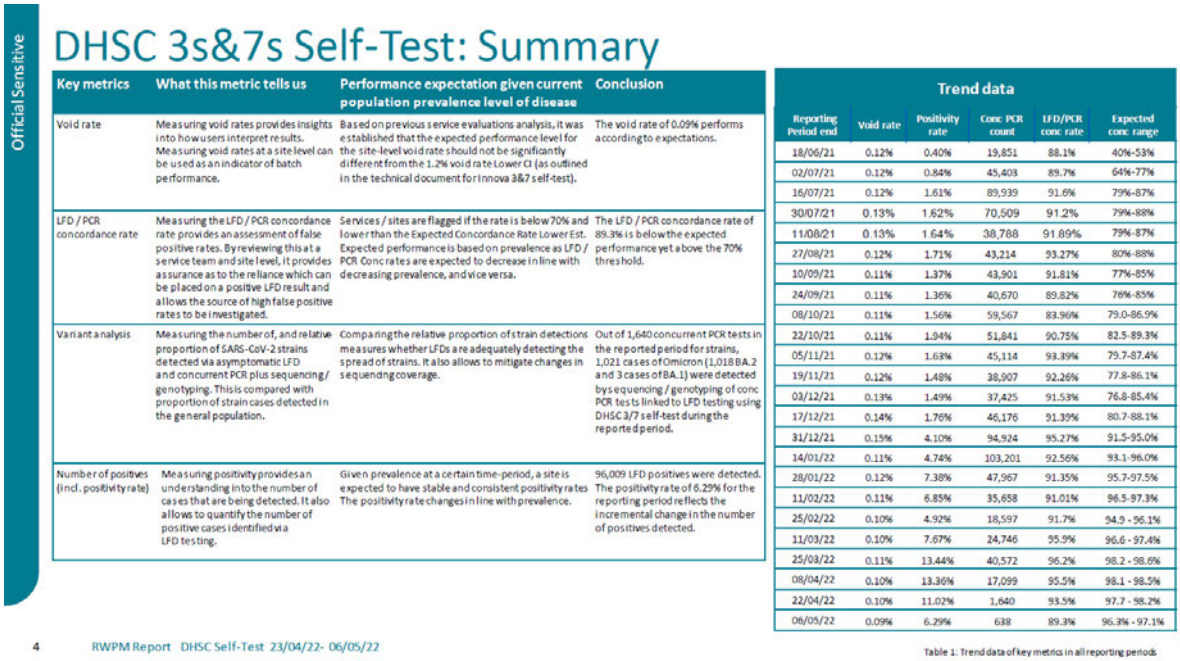
Trend data

Reporting Period end	Void rate	Positivity rate	Conc PCR count	LFD/PCR conc rate	Expected conc range
18/06/21	0.12%	0.40%	19,851	88.1%	40%-53%
02/07/21	0.12%	0.84%	45,403	89.7%	64%-77%
16/07/21	0.12%	1.61%	89,939	91.6%	79%-87%
30/07/21	0.13%	1.62%	70,509	91.2%	79%-88%
11/08/21	0.13%	1.64%	38,788	91.89%	79%-87%
27/08/21	0.12%	1.71%	43,214	93.27%	80%-88%
10/09/21	0.11%	1.37%	43,901	91.81%	77%-85%
24/09/21	0.11%	1.36%	40,670	89.82%	76%-85%
08/10/21	0.11%	1.56%	59,567	83.96%	79.0-86.9%
22/10/21	0.11%	1.94%	51,841	90.75%	82.5-89.3%
05/11/21	0.12%	1.63%	45,114	93.39%	79.7-87.4%
19/11/21	0.12%	1.48%	38,907	92.26%	77.8-86.1%
03/12/21	0.13%	1.49%	37,425	91.53%	76.8-85.4%
17/12/21	0.14%	1.76%	46,176	91.39%	80.7-88.1%
31/12/21	0.15%	4.10%	94,924	95.27%	91.5-95.0%
14/01/22	0.11%	4.74%	103,201	92.56%	93.1-96.0%
28/01/22	0.12%	7.38%	47,967	91.35%	95.7-97.5%
11/02/22	0.11%	6.85%	35,658	91.01%	96.5-97.3%
25/02/22	0.10%	4.92%	18,597	91.7%	94.9 - 96.1%
11/03/22	0.10%	7.67%	24,746	95.9%	96.6 - 97.4%
25/03/22	0.11%	13.44%	40,572	96.2%	98.2 - 98.6%
08/04/22	0.10%	13.36%	17,099	95.5%	98.1 - 98.5%
22/04/22	0.10%	11.02%	1,640	93.5%	97.7 - 98.2%

Table 1: Trend data of key metrics in all reporting periods

4 RWPM Report DHSC Self-Test 09/04/2022 – 22/04/2022

Figure 5: DHSC 3/7 self-test summary Period 9th Apr to 22-Apr-2022



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LFD / PCR concordance rate	Measuring the LFD / PCR concordance rate provides an assessment of false positive rates. By reviewing this at a service team and site level, it provides assurance as to the reliance which can be placed on a positive LFD result and allows the source of high false positive rates to be investigated.	Services / sites are flagged if the rate is below 70% and lower than the Expected Concordance Rate Lower Est. Expected performance is based on prevalence as LFD / PCR Conc rates are expected to decrease in line with decreasing prevalence, and vice versa.	The LFD / PCR concordance rate of 89.3% is below the expected performance yet above the 70% threshold.
Variant analysis	Measuring the number of, and relative proportion of SARS-CoV-2 strains detected via asymptomatic LFD and concurrent PCR plus sequencing / genotyping. This is compared with proportion of strain cases detected in the general population.	Comparing the relative proportion of strain detections measures whether LFDs are adequately detecting the spread of strains. It also allows to mitigate changes in sequencing coverage.	Out of 1,640 concurrent PCR tests in the reported period for strains, 1,021 cases of Omicron (1,018 BA.2 and 3 cases of BA.1) were detected by sequencing / genotyping of conc PCR tests linked to LFD testing using DHSC 3/7 self-test during the reported period.
Number of positives (incl. positivity rate)	Measuring positivity provides an understanding into the number of cases that are being detected. It also allows to quantify the number of positive cases identified via LFD testing.	Given prevalence at a certain time-period, a site is expected to have stable and consistent positivity rates The positivity rate changes in line with prevalence.	96,009 LFD positives were detected. The positivity rate of 6.29% for the reporting period reflects the incremental change in the number of positives detected.

Trend data

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22/04/22	0.10%	11.02%	1,640	93.5%	97.7 - 98.2%
06/05/22	0.09%	6.29%	638	89.3%	96.3% - 97.1%

Table 1: Trend data of key metrics in all reporting periods

4 RWPM Report DHSC Self-Test 23/04/22- 06/05/22

Figure 6: DHSC 3/7 self-test summary Period 23rd Apr to 06-May-2022

(Refer to Attachments 3.1 & 3.2)

6.8 Post Market Performance Follow Up

DHSC has implemented a series of ongoing evaluations. The objective of these evaluations is to determine whether lateral flow device (LFD) performance seen in pre-deployment evaluations are achieved when deployed by the testing service and to ensure that these continue to be suitable for use in services offered by NHS Test and Trace.

PMPF Report 2 was submitted to the MHRA 15th Apr 2022, titled "BIOTIME ongoing evaluation and DHSC 3&7 self-test post-market clinical performance follow-up report 2" and published on 14 Apr 2022 and covering the period 22 May 2021 – 21 Sep 2021.

A summary of the conclusions and findings of Report 2 is summarised below.

"In line with applicable regulatory requirements for PMCPF at the time of writing, the aims of this performance evaluation are addressed here:

f. To confirm the safety and performance of Biotime LFD throughout its expected lifetime

Performance across key device performance metrics in Report 2 and All Time was, for the prospective archetypes (1, 4, 5), considered not different to, or better than, those in the service evaluations that set the baseline performance for the Biotime LFDs when used by services within NHS T&T, except for PPV in archetype 5. In the retrospective archetypes (2&3), sensitivity was inferior and statistically lower. All other metrics were not different or higher. The inferior sensitivity in these archetypes triggered the conduct of a Root Cause Analysis and Risk Assessment from which it was found that this reduction in sensitivity is a data artefact driven by the longitudinal testing regime itself.

The testing regime involves taking a PCR and LFD on the first day of the shift pattern plus a midweek standalone LFD. The regular nature of the testing regime means that PCRs pick up infected individuals with lower viral concentrations at which LFD are known to be less sensitive. The standalone LFD result is not included in the sensitivity calculation as it doesn't have a same-day PCR to compare to. However, a positive midweek LFD result means an individual no longer takes part in dual testing. This is very different to the population in the study used to set baseline performance (LFD002), where the subjects had no recent history of testing. However, this also shows that the midweek LFD is a useful part of the testing regime in identifying potentially infectious individuals and removing them from care homes.

Accounting for the above differences identified in the Root Cause Analysis brought the reconciled sensitivity figure to within the lower confidence interval of the baseline study. As such, the risk this observed difference in sensitivity poses to ASC settings is brought within acceptable levels. This led us to conclude that it is physically and biologically implausible that ASC staff would see differential performance, and that any remaining non-quantifiable difference is clinically insignificant and caries little risk to use of the devices in this setting.

The report, "RWD002: Root cause analysis of observed sensitivity of LFDs below that of pre-deployment expected baseline performance when used by Adult Social Care staff. 4th March 2022" has been shared with MHRA.

Based on the above, it is concluded that the LFD continues to demonstrate acceptable performance consistent with its intended use.

g. To identify previously unknown risks or limits to performance and contra-indications to changing epidemiological factors e.g., variants, vaccination status, prevalence

No difference in performance has been observed for the key epidemiological factors other than in Archetype 3 where there is a significant difference considering individuals who are doubly vaccinated. This is not observed in any of the prospective datasets and as referenced in the ASC Staff Root Cause Analysis report24 is believed to be a data artefact driven by the testing regime as it is biologically implausible for there to be a difference in this population alone. It should be noted that archetypes 2 & 3 rely on data derived from longitudinal testing regimes. UKHSA is exploring how better to better analyse longitudinal testing regime data as part of post-market surveillance activities for these archetypes going forward.

h. To identify and analyse emergent risks based on factual evidence

There are factors which can introduce new risks such as variant and vaccination which have been considered within this report and shown not to be a concern. As such no additional risks have been identified through the conduct of this evaluation. When new variants emerge, this risk is addressed through a combination of in vitro evaluation, enhanced monitoring of device performance, and ultimately OE/ PMCPF.

i. To ensure the continued acceptability of the clinical evidence and of the benefit-risk ratio

With performance equivalent to or better than those in the baseline performance and following the ASC Staff Root Cause Analysis and Risk Assessment Report, the Biotime LFD remains appropriate for use as a public health intervention to reduce the impact of the SARS-CoV-2 pandemic in all archetypes assessed. The report is now available: “RWD002 Root cause analysis of observed sensitivity of LFDs below that of pre-deployment expected baseline performance when used by Adult Social care staff (4th March 2022)”

j. To identify possible systematic misuse.

No evidence of systematic misuse was identified based on the findings of this evaluation noting that VC adjusted and unadjusted sensitivity in all prospective archetypes (Archetypes 1,4,5) was not different from, or better than the sensitivity in the baseline studies (LFD001, LFD002) and as such leads to the conclusion that there is no widespread systematic misuse of the devices. In addition, incidents are regularly monitored via a combination of Real-World Performance Monitoring, complaints, and incidents process, which are the main route to identify any possible systematic misuse. These are included in UKHSA LFD PSR reports which are sent to MHRA monthly.

The information generated as part of this post-market performance follow-up evaluation provides continued confidence that the kits utilising the Xiamen Biotime LFD cassette, the DHSC 3&7 self-test kits, continue to provide sufficient diagnostic performance for use as part of a public health intervention within NHS Test & Trace to curb the spread of the SARS-CoV-2 pandemic.”

6.9 Variants of Concern (VOC)

The Variant of Concern Assurance Group (VOC) within the UKHSA are responsible for continuous monitoring of SARS-COV-2 variants. No new updates were received in time for this reporting window.

A cross-functional VOC meeting has now been setup and the Regulatory & Quality team are in attendance. Due to the recent structural and workforce changes at the UKHSA, there has been some inevitable delays in assessing appropriate VOC inclusion in the PSR. However, this is in progress and further updates will be provided via the periodic summary report submission.

6.10 CAPA

- Refer to Table 3 for a CAPA Status Overview
- Table 4 for List of open CAPA's and current progress and due dates.

CAPA Status	No
VOE	01
Open	01

Table 3: CAPA Status Overview

No	CAPA No	Start Date	Source	Problem statement	Status/ progress	Due date	Reason for extension if overdue
26	CAPA-21-06-0039	26-Nov-21	PMS Activities	CAPA raised due to a spike in LFD complaints taking them over the acceptable threshold	Complete pending VOE	VOE due 1st July 2022	N/A
27	CAPA-22-01-0041	05-Jan-2022	PMS Activities	CAPA raised due to batch of SureScreen kits failing Intertek validation.	Open	30-June-2022	Due date has been extended due to the volume of SCLSOP's that need updating for CAPA to be effective.

Table 4: List of open CAPA's, Status & Due date

6.11 SCAR – Supplier Corrective Action Report

No new SCARs were raised by DHSC to Innova for this reporting period. It is important to note that no new EUA stock will be ordered from Innova. Any actions from existing SCARs will not be realised as all stock is already received by UKHSA. SCARs are being raised to support the supplier to continuously improve processes.

6.12 Risk Management

LFD Risk management File (RMF) was updated to RMF-0001 Revision 5 and HTM Hazard traceability Matrix Rev5 ***(Refer to Attachment 04)***. The RMF updated to new template for compliance with ISO 14971:2019

No new Hazards were identified during this reporting period as part of the continual monitoring through post-market surveillance activities.

6.13 Literature Review & State of the Art (SOTA)

In collaboration with an external consultancy, DHSC has developed a Literature Search Protocol. The intention of the literature search is to review the continued clinical safety and effectiveness of the Lateral Flow Device kit when used for the intended purpose. Furthermore, the MedBoard platform is utilized to obtain current data on incidents, Field Safety Corrective Actions (FSCAa), etc. reported to or by regulatory agencies internationally.

The literature search & SOTA search is carried out monthly in line with the PSR reporting schedule and utilizes multiple electronic search databases (e.g., PubMed, Embase & Medboard) as highlighted in the protocol. It is worth highlighting that due to the frequency and timing of the LFD PSR reports, it is not practical nor feasible to provide a detailed analysis and conclusions of findings from the literature search report. However, the literature searches will be continuously reviewed with the support of PHCO for on-going performance evaluation and separately, a high-level summary is provided in the monthly PSR report.

The April update was conducted 09 May 2022. No new articles were determined to be relevant from neither the SOTA or safety and performance search.

(Refer to Attachment 07)

7. Conclusion & Risk-Benefit Determination

The DHSC LFD test is intended to detect the presence of coronavirus (Covid-19) antigen in humans to enable the spread of the virus to be reduced in the community. The overall purpose of post-market surveillance activities is to ensure that the device continues to meet its intended purpose.

Questions posed in the Post Market Surveillance plan (PMS-001) and at the beginning of this report have been addressed in **Table 5** and summarised in this section.

It is noted that performance of the device demonstrated a Void Rate of **0.10%** for the period between 9th Apr 2022 to 22nd Apr 2022 and 0.09% for the period between 23rd Apr 2022 to 06th May 2022, which performs according to expectations and is below the threshold of **1.2%.**

The confirmatory PCR rate of **93.5%** between the period of 9th Apr – 22nd Apr 2022 and **89.3%** between the period of 23rd Apr 2022 and 06th May 2022 which are above expected performance and provides assurance of positive LFDs confirmed by matched positive PCRs.

PMPF Report 2 was submitted to the MHRA 15th Apr 2022, titled "BIOTIME ongoing evaluation and DHSC 3&7 self-test post-market clinical performance follow-up report 2" and published on 14 Apr 2022 and covering the period 22 May 2021 – 21 Sep 2021. Findings from this report confirmed that the DHSC LFD performance is equivalent to or better than those in the baseline performance and following the ASC Staff Root Cause Analysis and Risk Assessment Report, the Biotime LFD remains appropriate for use as a public health intervention to reduce the impact of the SARS-CoV-2 pandemic in all archetypes assessed.

No new Hazards were identified during this reporting period as part of the continual monitoring through post-market surveillance activities. Hazards identified in the previous reporting period were assessed and there was no change in the risk acceptability policy.

DHSC has not instigated a re-call nor issued any Field Safety Corrective Action Notices during this reporting period.

No new relevant literature was found and no new Medboard SOTA literature was identified in Section 6.3 for this reporting period.

Based on the information discussed in this periodic summary report, the DHSC maintain the position that the benefits of use of Lateral Flow Devices continue to outweigh the risks identified in the risk management plan, these include:

a) Early indication of possible infection with Covid-19 while still asymptomatic
b) Prevention of spread of Covid-19 virus
c) Prevention of the need for unnecessary self-isolation/travel restriction therefore improving patient/user quality of life.
d) Widespread PCR testing is operationally unfeasible

Question	Answer	Comments	Evidence
a) Were there any new hazard or hazardous situation(s) identified for the DHSC LFD's or has the risk acceptability changed?	No	No new hazards identified in this reporting period.	**Section 6.12**
b) Has any misuse of the DHSC LFDs occurred?	No	No formal complaints or reports in Qualtrics received to indicate the DHSC LFD was misused.	**Section 6.3**
c) Do the DHSC LFD's still meet the user's needs after medium/long term clinical use?	Yes	On-going real-world performance monitoring indicates void rates below expected threshold and confirmatory PCR tests in line with expectations.	**Section 6.7** **Section 6.8**
d) Do users experience any usability issues?	No	Satisfaction rates are above 70% with regards to usability of the devices. Any minor issues identified are feeding into continuous improvement activities at the procurement stage.	**Section 6.5** **Section 6.6**
e) Are there any recurring quality issues DHSC LFD's and can significant increasing/decreasing trends be identified for DHSC LFD' inadequate performance?	No	Issues relating to missing items were observed. A SCAR has already been raised against Innova/Biotime. Immediate containment action not deemed necessary as the risk on patient safety is minimal. Any improvements by Innova will not be realised as all products are received by UKHSA.	**Section 6.4** **Section 6.11**

Table 5: Questions posed by PMS-001 Plan for DHSC LFD Products

No emerging issues or safety signals identified. As result of the PMS activities analysed/discussed in this report the PMS Team advice is to continue distributing the current EUA cleared product.

8. Recommended Actions

No	Added	Action	Responsible Name	Due Date	Status
1	19 May 2022	Raise a non-conformance report to capture the issue with one lot of LFD identified as part of the Intertek validation report.	[redacted]	16 June 2022	Active

9. Attachments

Attachment 01: PMS-0001, PMS Plan for the DHSC Covit-19 LFD Devices (3 and 7 kit) Rev2, 29-July-2021
Attachment 02: DHSC PSR – Complaints & Qualtrics data (Attachments 2.1 – 2.3)
Attachment 03: RWPM Innova 3s and 7s
Attachment 04: RWPM Innova 25's
Attachment 05: RWPM Innova Assisted
Attachment 06: QP08-F02 LFD Hazard Traceability Matrix v.01 Issued 22.12.2021
Attachment 07: Inbound Freight Data (Attachments 5.1 & 5.2)
Attachment 08: Literature Search Report - Lateral Flow Device 202204 without papers

10. Author

	Job Title	Name	Email
Compiled by	Post Market Surveillance Manager	[redacted]	[redacted]